UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,192	07/02/2003	Ranajit Pal	502615.20014	4134

26418 7590 09/22/2010

REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER	
PENG, BO	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,192	PAL ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) *8-14 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 10, 2010, has been entered.

2. Claims 1-14 and 16-21 are pending. Claims 8-14 and 16-20 have been withdrawn from consideration as nonelected inventions. Claims 1-7 and 21 are considered in this Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. (**Prior rejection-maintained and restated** necessitated by the amendment)

Claims 1-7 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting over Claim 1 of US patent **5,843,454 ('454)**, and Claim 1 of US **5,518,723 ('723)**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-7 and 21 of the instant application is obvious over the invention of US Pat. Nos. '454 and '723, in view of Vita (PNAS, 96(23):13091-13096; 1999).

4. The instant application is CIP of 09/905,962, filed on July 2, 2003. It is noted that there is not support in 09/905,962 for "a fragment of CD4 includes either the first domain of CD4, the second domain of CD4, both the first and second domains of CD4, or a combination of the first or second domain of CD4 and the third or fourth domain of CD4" The priority date of the Claims 1-7, 15 and 21 of the instant application is determined as July 3, 2003.

5. Claim 1 of '454 or a'723 teaches an immunogenic complex comprising gp120 covalently bonded to CD4. The specification of both '454 and '723 teach a complex of gp120 and soluble CD4 (sCD4). sCD4 is known to be a fragment of CD4, which comprises CD4 domains 1-4 (D1 –D4). The specification of both '454 and '723 also teach that the binding of gp120 and sCD4 exposes cryptic epitopes, which are critical for inducing antibodies against post-binding fusion events of HIV infection; see e.g. Para 1 of "Detailed Description of the Embodiments". However, neither '454 nor '723 explicitly teach a complex comprising gp120 and a fragment of CD4, including D1 or D2; or a combination of D1 or D2 of CD4 and D3 or D4 of CD4.

6. Vita teaches that D1, D2 domains and Arg59 of CD4 are essential for interact with gp120; see para 1, 2 and 3, p. 13091 and Fig. 1. Vita shows that CD4 fragments, like

"mini-CD4" comprising D1 or D2 domains, have higher infinity for gp120 than sCD4 fragment, see e.g. Abstract. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immunogenic complex of Claim 1 of '454 and '723 by incorporating CD4 fragments, including first or second domain or a combination thereof, which are responsible for binding gp120. The skilled artisan would have been motivated to do use CD4 fragments, as equivalent to CD4 molecule, and would have a reasonable expectation of success, given that D1, D2 and other domains are responsible for CD4 binding to gp120, and also given that these CD4 fragments have higher affinity to gp120, as taught by Vita. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

In response to Applicant's argument:

7. Applicant asserts that the argues that Claims 1-7, 15 and 21 of the instant application is patently distinct form Claim 1 of '454 and '723, because Claim1 of '454 and 723 is directed to a complex of gp120 covalently bonded to entire CD4, but not a fragment of CD4.

8. This argument is not persuasive for the reason set forth in Para 4-6 above. The rejection is maintained.

9. (**New rejection**) Claims 1-7 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting over Claim 1 of US Pat. **6,328,973** ('973). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-7 and 21 of the instant application is obvious over the invention of US

Pat. '973, in view of Vita (PNAS, 96(23):13091-13096; 1999).

10. Claim 1 of "973 is drawn to a method of raising neutralizing antibody using a immunogenic complex of gp120 covalently bonded to CD4. The specification of '973 teaches that an immunogenic complex of gp120 covalently bonded to sCD4, which includes domains 1-4 of CD4, can induce neutralizing antibody. '973 also teaches that interaction of gp120 and sCD4 exposes cryptic epitopes, which are critical for inducing antibodies aginst post-binding fusion events of HIV infection; see e.g. Para 1 of "Detailed Description of the embodiment". "973 does not explicitly use of a immunogenic complex of gp120 covalently bonded to a fragment of CD4, including D1 or D2 fragment; or a combination of D1 or D2 of CD4 and D3 or D4 of CD4 of CD4 fragments, to induce an neutralizing antibody to HIV.

11. The relevance of Vita is set forth *supra*.

12. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the claimed complex of gp120 and CD4 fragments responsible for binding gp120 in order to induce neutralizing antibody to HIV as taught by Claim 1 of '973. The skilled artisan would have been motivated to use such CD4 fragments, as equivalent to CD4 molecule, and would have a reasonable expectation of success, given that D1, D2 and other domains are responsible for CD4 binding to gp120, and also given that these CD4 fragments have higher affinity to gp120, as taught by Vita. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

13. **This rejection is necessitated by the decision of the Court of Appeals for the Federal Circuit in Pfizer Inc. v Teva pharmaceuticals USA Inc., 86 USPQ2d 1001, at**

page 1008 (March 2008), which indicates that there is no patentable distinction between claims to a product and a method of using that product disclosed in the specification of the application and that the preclusion of such a double patenting rejection under 35 USC 121 does not apply where the present application is other than a divisional application of the patent application containing such patentably indistinct claims. It is noted that the instant application is a CIP of 09/905,962, which is CON of US Pat'973. The instant application is neither a DIV nor a CON of US Pat '973.

Remarks

14. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648